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EXAMINER

PALENIK, JEFFREY T

ART UNIT

PAPER NUMBER

1615

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/519,484

**Applicant(s)**

NISHIBE ET AL.

**Examiner**

Jeffrey T. Palenik

**Art Unit**

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 4 and 5 is/are pending in the application.
- 4a) Of the above claim(s) 4 and 5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

### **DETAILED ACTION**

Receipt is acknowledged of Applicants' Request for Continued Examination (RCE) filed 21 January 2009. The Examiner acknowledges the following:

Applicants' amendments and remarks have been entered.

Claims 1, 4 and 5 remain pending in the application.

Claims 4 and 5 remain withdrawn from consideration as being drawn to a non-elected invention.

Claims 2, 3 and 6-9 are cancelled.

Claim 1 has been amended such that it now incorporates the limitations of cancelled claims 2 and 3 wherein the aqueous ciclesonide suspension further comprises hydroxypropyl methylcellulose (HPMC) and more specifically, HPMC 2910.

No new claims have been added. No new matter has been added.

Thus, claim 1 now represents the only claim currently under consideration.

### **INFORMATION DISCLOSURE STATEMENT**

One new Information Disclosure Statement (IDS), filed 5 August 2008, is acknowledged and has been considered.

### **WITHDRAWN OBJECTIONS/REJECTIONS**

#### **Objection to the Specification**

Applicants' amendments to the Abstract of the Invention render the objection to the Specification moot. Thus, said objections have been withdrawn.

Rejection under 35 USC 102(b)

Applicants' amendment to claim 1, as discussed above, renders moot the rejection to claim 1, under 35 USC 102(b), as being anticipated by Karlsson et al. (US Pre-Grant Publication N° 2002/0065256). Thus, said rejection now stands **withdrawn**.

**MAINTAINED REJECTIONS**

The following rejections are maintained from the previous Office Action dated 21 October 2008:

**CLAIM REJECTIONS - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Karlsson et al. (U.S. Patent Publication 2002/0065256) in view of the Material Safety Data Sheet (MSDS) for Metolose 60SH.

Karlsson et al. teaches the ciclesonide and HPMC suspension, as described above. Said teachings from the withdrawn rejection under 35 USC 102(b) are reproduced here for Applicants' convenience:

*The composition is taught by Karlsson et al. at claims 7, 9, and 10. Claim 10 teaches a thickening agent which is further defined as including hydroxypropyl methylcellulose (see [0040] and [0041]).*

However, Karlsson does not teach the specific grade of HPMC (HPMC 2910) as cited in claim 3. Per Applicants' specification, the claimed HPMC 2910 is also known industrially as Metolose 60SH. Shin-Etsu Co. produces the HPMC of the present invention and provides an MSDS which further provides a Recommended Use for Metolose 60SH as a thickening agent.

Since the ingredient of the composition is the chemically the same, it follows that particular grade of HPMC used is a result-effective parameter that a person having ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to employ the optimal grade hydroxypropyl methylcellulose within the composition in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, optimization of this ingredient would have been obvious at the time of Applicant's invention.

#### RESPONSE TO ARGUMENTS

Applicants' arguments with regard to the rejection of claim 1 under 35 USC 103(a) as being unpatentable over Karlsson et al. in view of the Material Safety Data Sheet (MSDS) for Metolose 60SH, has been fully considered, but is not persuasive.

Applicants argue that a *prima facie* case of obviousness has not been established "because there is no apparent reason to prompt a person of ordinary skill in the art to combine the elements disclosed in the cited references". Applicants further allege that any *prima facie* case of obviousness is rebutted by the data presented. Applicants direct the Examiner's attention specifically to Table 3 on page 14 and Example 2 of the present specification as evidence that the instantly claimed composition achieves an improvement in content uniformity over preparations using other wetting agents.

In response, the Examiner respectfully submits that Applicants' amendment to independent claim 1 and remarks thereto, are not persuasive. First, the combined teachings above discuss a sterile suspension of ciclesonide and HPMC. Though Karlsson does not expressly teach the use of HPMC 2910, it would have been within the purview of the skilled artisan to employ it. That said, Applicants' evidence is unpersuasive simply because Example 2, which is prepared using the wetting agent HPMC 2910 (i.e. HPMC), is contrasted against five other comparative formulations of ciclesonide, none of which employ a different form of HPMC. The other wetting agents used are: Tween 80 (Comp. Ex. 3), Tween 60 (Comp. Ex. 4), Polyoxyethylene Hydrogenated Castor Oil 60 (Comp. Ex. 5), Hydroxypropyl cellulose (HPC) (Comp. Ex. 6), and Carmellose Sodium (Comp. Ex. 7). Since no comparative evidence between HPMC 2910 or any other form of HPMC has been presented, the Examiner concludes that

Applicants have failed to provide any evidence which would suggest that the ordinarily skilled artisan would not have been motivated to employ HPMC 2910 in the invention practiced by Karlsson et al.

Furthermore, it should be noted that there is no clear discussion within the present specification as to what constitutes “Example 2”. It appears that “Investigation 2” provides a ciclesonide/HPMC 2910 preparation, the properties of which are contrasted against the aforementioned Comparative Examples 3-7. Thus, for the purposes of reconciling Applicants’ response, the Examiner interprets Applicants’ discussion of “Example” as being directed to the preparation of “Investigation 2”.

Thus, for these reasons, Applicants’ arguments are found unpersuasive. Said rejection is **maintained**.

#### **REQUEST FOR REJOINDER OF WITHDRAWN CLAIMS**

Regarding Applicants’ request for rejoinder of withdrawn claims, said claims will not be rejoined since the instantly amended product claim is not considered as being in a condition for allowance.

#### **NEW REJECTIONS**

In light of Applicant’s amendment to claim 1, the following rejections have been newly added:

**CLAIM REJECTIONS - 35 USC § 112**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 contains the trademark/trade name hydroxypropylmethylcellulose 2910. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe hydroxypropyl methylcellulose and, accordingly, the identification/description is indefinite.

**CLAIM REJECTIONS - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.



The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Karlsson et al. and Nagano et al. (WO 01/28563 A1).

The instantly amended claim 1 is directed to an aqueous suspension comprising ciclesonide and hydroxypropylmethylcellulose 2910 which is sterilized via autoclaving and wherein the resulting preparation comprises at least 95% ciclesonide. Per MPEP §2113, product-by-process limitations hold no patentable weight. Thus, regardless of how the instantly claimed ciclesonide-containing aqueous suspension is made sterile, the fact still remains that a sterile ciclesonide-containing aqueous suspension results.

The teachings to Karlsson et al. are discussed above. Again, Karlsson does not expressly teach using HPMC 2910.

The invention practiced by Nagano et al. is directed to an aqueous pharmaceutical composition containing ciclesonide and HPMC, wherein the ciclesonide is dispersed (e.g. suspended in an aqueous medium in the form of solid particles (Abstract). Compositions 1-5 of Example 1, expressly teach aqueous formulations comprising both ciclesonide and HPMC 2910. Ciclesonide concentration of the preparations was evaluated as being 100% (pg. 7, lines 26-34).

It would have been *prima facie* obvious to a person having ordinary skill in the art at the time the invention was made to have added HPMC 2910 to the invention of Karlsson et al. as a form of HPMC to be mixed and sterilized with ciclesonide. As discussed before, absent any evidence to the contrary (i.e. physical or chemical differences between HPMC 2910 and HPMC), the ordinarily skilled artisan would have been motivated to substitute one compound for the other and would have still had a high expectation of successfully arriving at the instantly claimed invention.

All claims have been rejected; no claims are allowed.

#### CORRESPONDENCE

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966. The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey T. Palenik/  
Examiner, Art Unit 1615

/MP WOODWARD/  
Supervisory Patent Examiner, Art Unit 1615